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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,468	09/29/2005	Reinhard Walther	BJS-35-289	7315

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,468	WALTHER, REINHARD	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-2, drawn to a method of identifying a substance suitable for influencing interaction of one or several proteins from SEQ ID NO: 4, 6, 8, 10, protein EED or fragments thereof and a protein of SEQ ID NO: 2 (PDX-1).

Group 2, claim(s) 3 drawn to a method of identifying a substance suitable for influencing interaction of one or several proteins from SEQ ID NO: 4, 6, 8, 10, protein EED or fragments thereof and a protein of SEQ ID NO: 2 (PDX-1), wherein PDX-1 is immobilized on a microtiter plate.

Group 3, claim(s) 4-8, as drawn to a pharmaceutical composition comprising a substance, wherein said substance **modulates the activity** of a protein selected from SEQ ID NO: 4, 6, 8, 10 and protein EED; and a method of making the same.

Group 4, claim(s) 4-8, as drawn to a pharmaceutical composition comprising a substance, wherein said **substance binds** to a protein selected from SEQ ID NO: 4, 6, 8, 10, protein EED or a fragment of said proteins and a method of making the same.

Group 5, claim(s) 4-8, as drawn to a pharmaceutical composition comprising a substance, wherein said **substance phosphorylates** a protein selected from SEQ ID NO: 4, 6, 8, 10 and protein EED and a method of making the same.

Group 6, claim(s) 4-8, as drawn to a pharmaceutical composition comprising a substance, wherein said substance increases the proportion of a protein selected from SEQ ID NO: 4, 6 and 8 and a method of making the same.

Group 7, claim(s) 9-10, drawn to a pharmaceutical composition comprising one or more proteins selected from SEQ ID NO: 4, 6, 8 (CKII), 10 (14-3-3 epsilon), EED and fragments thereof; and methods of making the same.

Group 8, claim(s) 11, drawn to a pharmaceutical composition comprising one or more nucleic acids selected from SEQ ID NO: 3, 5, 7, 9 and or one or more nucleic acids that encode EED for modulating the synthesis of insulin in an individual.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Freister et al (see X references (i) WO 02062954 A (US Patent No. 6,440,738) disclose special technical feature of Casein Kinase II polypeptide and nucleic acid sequence encoding the CKII polypeptide (e.g., aa 1-15 of SEQ ID NO: 17 of US Patent No. 6,440,738 and aa 1-15 of the SEQ ID NO:8 of the instant application are identical). Therefore, Inventions 1-8 lack a special technical feature and cannot share one with the other inventions.

Group 1, recites the special technical feature of identifying a substance suitable for influencing interaction of one or several proteins from SEQ ID NO: 4, 6, 8, 10, protein EED or fragments thereof and a protein of SEQ ID NO: 2 (PDX-1).

Group 2, recites the special technical feature of identifying a substance suitable for influencing interaction of one or several proteins from SEQ ID NO: 4, 6, 8, 10, protein EED or fragments thereof and a protein of SEQ ID NO: 2 (PDX-1), wherein PDX-1 is immobilized on a microtiter plate, which is not required by the methods of Group 1.

Group 3, recites the special technical feature of a pharmaceutical composition comprising a substance, wherein said substance **modulates the activity** of a protein selected from SEQ ID NO: 4, 6, 8, 10 and protein EED; and a method of making the same, which is not required by the products of Groups 4-8.

Group 4, recites the special technical feature of a pharmaceutical composition comprising a substance, wherein said **substance binds** to a protein selected from SEQ ID NO: 4, 6, 8, 10, protein EED or a fragment of said proteins and a method of making the same, which is not required by the products of Groups 3 and 5-8.

Group 5, recites the special technical feature of a pharmaceutical composition comprising a substance, wherein said **substance phosphorylates** a protein selected from SEQ ID NO: 4, 6, 8, 10 and protein EED and a method of making the same, which is not required by the products of Groups 3-4 and 6-8.

Group 6, recites the special technical feature of a pharmaceutical composition comprising a substance, wherein said substance increases the proportion of a protein selected from SEQ ID NO: 4, 6 and 8 and a method of making the same, which is not required by the products of Groups 3-5 and 7-8.

Group 7, recites the special technical feature of a pharmaceutical composition comprising one or more proteins selected from SEQ ID NO: 4, 6, 8 (CKII), 10 (14-3-3 epsilon), EED and fragments thereof and methods of making the same, which is not required by the products of Groups 3-6 and 8.

Group 8, recites the special technical feature of a pharmaceutical composition comprising one or more nucleic acids selected from SEQ ID NO: 3, 5, 7, 9 and or one or more nucleic acids that encode EED for modulating the synthesis of insulin in an individual, which is not required by the products of Groups 3-7.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Further Restriction/Election

Groups 1-7

If Group 1, 2, 3, 4, 5, 6 or 7 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

The inventions Groups 1-7 pertain to a number of polypeptides identified either by name or a SEQ ID Number (i.e., EED or SEQ ID NO: 4, 6, 8 or 10).

Each of the claimed polypeptide fragments are composed of amino acid units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching two claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. **Therefore, Applicant must choose a single polypeptide either by name, for example EED; or by SEQ ID Number (e.g., SEQ ID NO: 4, 6, 8 or 10) from the group against which the search should be performed.**

Group 8

If Group 8 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

The inventions Group 8 pertains to a number of polynucleotide encoding a polypeptide fragment listed in claim 11 (i.e., polynucleotides encodingEED or a nucleic acid sequence of SEQ ID NO: 3, 5, 7 or 9).

Each of the claimed nucleic acid sequences are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence or gene requires a unique separate search of the prior art. Searching two claimed sequences or genes would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches**. Therefore, Applicant must choose either a nucleic acid that encodes for EED or a nucleic acid sequence from SEQ ID NO: 3, 5, 7 or 9 against which the search should be performed.**

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicant elects Group 1, 2, 3, 4, 5, 6 or 7, a single polypeptide either by name (e.g., EED) or by a sequence identifier number (e.g., SEQ ID NO: 4) must be

identified to be fully responsive. If applicant elects Group 8, a single nucleic acid sequence (e.g., SEQ ID NO: 3) or a nucleic acid that encodes for a protein (e.g., EED) must be identified to be fully responsive. It is noted that the election of a peptide for Groups 1-7; or the election of a nucleic acid for Group 8 is a restriction election and not a species election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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21 February 2008
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/Robert Landsman/
Primary Examiner, Art Unit 1647